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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,169	09/09/2003	Jae-Hoon Lee	YPL-0061	3342
7590	06/21/2005		EXAMINER	
Michael A. Cantor 55 Griffin South Road Bloomfield, CT 06002			NATALINI, JEFF WILLIAM	
			ART UNIT	PAPER NUMBER
			2858	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

EK

Office Action Summary

Application No.

10/658,169

Applicant(s)

LEE ET AL.

Examiner

Jeff Natalini

Art Unit

2858

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The new amendment to claim 1 describes a PCR reaction being performed in the absence of an ionically-labelled probe, but it does not provide any indication the steps taken to perform PCR without an ionically-labelled probe. Also no specific examples of an ionically-labelled probe are disclosed so that one skilled in the art would easily recognize that PCR is performed in the absence of a ionically-labelled probe. The steps of the reaction must be clearly defined so that one skilled in the art will be able to make use of the invention and for showing that it is patentably distinct from the prior art. Applicant is advised to provide examples of an "ionically-labelled probe" and provide in the claim a description of the steps taken in the PCR, defining over the prior art. The rejection that follows is what is best understood from the claims.

Claim Objections

2. Claims 10 and 11 are objected to because of the following informalities:

These claims refer to a predetermined frequency, but it is unclear by reading the claims, it is unclear as to what is at a predetermined frequency. By reading the specifications where there is support for the amendment it seems as though the AC

voltage is at this predetermined frequency and the claims will be examined as that were the case.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Blackburn et al. (6264825).

In regard to claim 1, Blackburn et al. discloses a method for detecting a polymerase chain reaction (PCR) product (col 88 line 5-7) comprising:

providing at least a pair of electrodes (col 88 line 8-15) in a PCR solution containing vessel (col 90 line 38-42);

performing PCR (col 87 line 60- col 88 line 15) in the absence of an ionically-labelled probe Blackburn et al. never discloses anything about using an ionically-labeled probe and even talks about non-ionic nucleic acid (col 9 line 7-11) ;

producing an electric field between the electrodes (col 83 line 65 – col 84 line 14); and

measuring a change in a dielectric property in a PCR solution (col 83 line 49-55; bulk impedance is known in the art to be the dielectric property of impedance of the solution between the two electrodes).

In regard to claim 2, Blackburn et al. discloses wherein step (b) the PCR is performed in the absence of an ionically-labeled primer (Blackburn et al. never discloses anything about using an ionically-labeled primer and even talks about non-ionic nucleic acid (col 9 line 7-11)).

In regard to claim 3, Blackburn et al. discloses where the PCR solution-containing vessel is a PCR tube (col 90 line 38-42).

In regard to claim 4, Blackburn et al. discloses wherein the dielectric property is impedance (col 83 line 49-55; bulk impedance is known in the art to be the dielectric property (col 1 line 38-40) of impedance of the solution between the two electrodes).

In regard to claim 5, Blackburn et al. discloses wherein the electric field is produced using an alternating current at a frequency of 1 Hz to 100MHz (col 84 line 11-14).

In regard to claim 6, Blackburn et al. discloses wherein the electric field is produced using an average AC voltage of 1mV to 10V (col 84 line 7-11).

In regard to claim 7, Blackburn et al. discloses wherein the PCR solution-containing vessel includes a PCR tube (col 90 line 38-42), and the electrodes are installed to be opposite to each other at a predetermined height from a bottom of the PCR tube (fig 1E, electrodes (20) are opposite each other at a determined height).

In regard to claim 8, Blackburn et al. discloses wherein the PCR solution-containing vessel includes polymerization microchamber (fig 1 or 2 shows a chamber where polymerization occurs), where electrodes are installed at upper and lower sides of the microchamber (fig 2 shows upper side electrodes (12, 13) and lower side electrodes (17,16)).

In regard to claim 9, Blackburn et al. discloses connecting an impedance sensor to the electrodes to measure a change in an impedance magnitude with an increase in PCR cycles (col 81 line 49-55 says the change in impedance is 'monitored', this change will occur over time/PCR cycles).

In regard to claims 10 and 11, Blackburn et al. discloses connecting an impedance sensor to the electrodes to measure a change in an impedance magnitude with an increase in PCR cycles (col 81 line 49-55 says the change in impedance is 'monitored', this change will occur over time/PCR cycles) with the AC voltage at a predetermined frequency of about 1000Hz (col 4 line 11-14).

Response to Arguments

5. Applicant's arguments filed April 13, 2005 have been fully considered but they are not persuasive. Applicant argues that the method of Blackburn is performed in the presence of ETM (electron transfer moiety). In making a negative claim (wherein the claim points out something that is lacking) applicant needs to point to a place in the prior art where the feature is seen, or it is assumed that the prior art also lacks this feature. Applicants argues that the method of Blackburn is performed in the presence of ETM,

but does not prove that this ETM is known in the art to be synonymous with an "ionically-labelled" probe, nor does the applicant give any examples in the instant invention of what an "ionically-labelled" probe consists of. A moiety halves or divides components of a substance. It is known practice that components of a substance (charge particles) move under the influence of an applied electric field therefore ETM would exist in any capacitance type measurement.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Woodenberg et al. (6126899) discloses where a PCR reaction mixer is prepared without primers and probes.

Zhang et al. (US pub 2003/0027169) discloses where PCR is performed without any primer if either a phosphatase and exonuclease I digestion is performed, also discloses electrodes to provide a field around the exit orifice.

Schmidt (4023096) discloses a chamber for a chemical process that contains electrodes that produce a field in the chamber and measure a change in impedance (capacitance) inside of the chamber.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

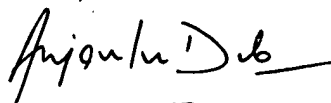
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Natalini whose telephone number is 571-272-2266. The examiner can normally be reached on M-F 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eddie Lefkowitz can be reached on 571-272-2180. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeff Natalini




ANJAN DEB
PRIMARY EXAMINER